

HRA CORPORATE RISK REGISTER: Risks 12 and above accepted by EMT

Version Control	Version	Jun-14	Board	Stephen Tebbutt	Date	04/06/2014
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HRA Risk Ref	Previous risk reference	Risk type	Date Raised	Last Reviewed	Risk Description	Timing	Likelihood	Impact	RAG Status & Trend	Status Change	Risk Owner	Risk Mitigation and Intended Impact	Action Owner	Due date for actions	Target residual risk RAG status	Impacted Projects / Areas	Escalated	Assurance sources
HRA004	IMG 9 (HRA004)	formerly IMG	03/05/2013	07/05/2014	Risk: HRA unable to deliver to the level of expectation of stakeholders within its role to promote transparency in research Cause: Timescales of moving forward with stakeholders, interdependency of work streams, capacity and environment appetite for change whilst not disadvantaging UK Effect: Reputation of HRA damaged	Medium	3	4	12	↕	TS	RM1: Extensive engagement and position statement prepared in collaboration with stakeholders RM2: Easter 2014 - document re REC declaration and reporting/publication expectations issued for comment	TS	On-going	6	Business Plan		Preparing paper on reporting (publishing) and REC declaration in order to move forward with stakeholders to increase transparency whilst ensuring confidence
HRA001	IMG 10 (HRA005)	formerly IMG	03/05/2013	07/05/2014	Risk: HRA-led roles to improve research transparency in the UK perceived to make the UK a less attractive place to do research Cause: Transparency work 'appearing' to restrict researchers, increase 'red tape' and/or research burdens Effect: Reputation of HRA damaged with decrease in amount of research taking place in UK	Medium	3	4	12	↕	TS	RM1: Extensive engagement and proportionate approach agreed. RM2: Need to maintain effective communications and engagement recognised RM3: Feedback is being sought, via Phase 1 Group and website, for difficulties caused by requirement, since Sept '13, to register all clinical trials, to understand the extent to which UK may be becoming (or not) less attractive	TS	On-going	6	Business Plan		Preparing paper on reporting (publishing) and REC declaration in order to move forward with stakeholders to increase transparency whilst ensuring confidence. Have sought, via Phase 1 meeting and forthcoming HRA Latest to gather feedback on barriers to CT registration ahead of 2016 European requirements
HRA097	CORP 046 (HRA004)	IT	13/12/2012	07/05/2014	Risk: Unacceptable level of Atos/DH IT service Cause: Open Service offers a sporadic level of performance resulting in issues which have a significant impact on operations / services Effect: Disruptions to operations / services affecting performance and staff morale	Imminent	4	4	16	↓	TS	RM1: IT work off list being jointly managed by HRA, Atos and DH IT. RM2: DH SLA in place with Atos and escalation routes established between HRA and DH IT. RM3: Position continues to be monitored. RM4: Formal letter of dissatisfaction sent to DH which logs the issues and addressed issues of compensation. RM5: DH have issued an invoice which HRA is disputing. RM6: Letter sent from CE and Chair to DH ICT Feb '14 highlighting continued service impacts - response awaited. RM7: May '14 - more SLA KPIs are being met by provider	TS/NG	On-going	10	Business as usual: Operations and Business Unit services	Director IT DH	IT Project Team SDB CMG EMT
HRA167	N/A	HRA Approval	04/06/2014	04/06/2014	HR, Roles and TUPE There are a number of complex areas with regard to HR and the application of TUPE. These need working up in detail. There are linked dependencies with other organisations, particularly CRN which is hosted currently by the University of Leeds and also funds staff within the NHS.	Imminent	4	3	12	NEW	JM	The timing of the programme gives some time to identify and manage these issues and although significant to the HRA and the HRA programme, the NHS has responded to far more significant national policy changes. The HRA is building effective relationships with CRN to mitigate against these risks.	JM	TBC	8	HRA Approval		
HRA168	N/A	HRA Approval	04/06/2014	04/06/2014	Business continuity There are a number of complex issues and risks to business continuity which will need to be worked up in detail. These are for HRA (e.g. if staff move out of current operational roles to new project roles), and to others within wider R and D community.	Imminent	4	4	16	NEW	JM	Communications will be key and the HRA has good networks to operate within. The balance between having effective communications at an appropriate level (detailed vs. high level) will be a challenge. The HRA will look to take proactive action to mitigate risks. E.g. the HRA has ensured roles are available England wide rather than linked to HRA office geographies.	JM	TBC	10	BAU		

HRA169	N/A	HRA Approval	04/06/2014	04/06/2014	Metrics There are considerable challenges in the demonstration of success and expectation and the need for others to be able to have comparable metrics to show the value of the HRA Approval programme, and rapidly. Comparable metrics are not advisable given it is a new process not the improvement to an old one. The HRA will however have to provide line of sight to current metrics, not least the 70 days benchmark	Imminent	4	5	20	NEW	JM	The main opportunity will be to use funder and Industry timelines which currently measure more of the process in the UK, as well as case study examples of improvement as early good news stories and gathering evidence of front line savings through the early clinical review roll out.	JM	TBC	10			
HRA170	N/A	HRA Approval	04/06/2014	04/06/2014	Reputation and buy in There are considerable expectations of delivery and improvement. Some are realistic but considerably challenging whilst others are unrealistic. Confidence is high in the HRA which has a reputation of delivery, both of which need to be maintained.	Imminent	4	4	16	NEW	JM	Communication of realistic and achievable objectives. Early wins to demonstrate progress.	JM	TBC	10			
HRA171	N/A	HRA Approval	04/06/2014	04/06/2014	UK compatibility HRA Approval relates to England however researchers want, and the UK needs, UK wide compatibility. Later implementation (2016/17) of EU regulations will require it but the operational differences across the countries present navigational challenges.	Imminent	3	4	12	NEW	JM	UK commitment to a UK policy framework with strong links across to colleagues in the DA.	JM	TBC	8			UKECA 4 Nations RGF SG